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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,939	05/30/2001	Douglas A. Amorese	10010791-1	8714

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,939	AMORESE ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-20 and 38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 5-20 38-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 3 June 2004 in which claims 1 and 41 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 3 March 2004are maintained as discussed and reiterated below. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant rejections. New grounds for rejection, necessitated by amendment, are discussed.

Claims 1-3, 5-20 and 38-41 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Clontech (catalog page 26, 1995).

Regarding Claim 1, Clontech discloses an array of features comprising single stranded cDNAs of at least 400 nucleotides and a second set of features independent of the first set comprising synthetic polynucleotides of not more than 100 nucleotides (Figure 4.2)

Regarding Claim 9, Clontech discloses the array wherein the second set is in the corner of the rectangle (Fig. 4.2).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 5-10, 14, 38 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Bao et al (U.S. Patent No. 6,251,601, filed 2 February 1999) in view of Bobrow et al (U.S. Patent No. 6,399,299, filed 29 October 1999).

Regarding Claim 1, Bao et al disclose an array comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides and a second set of features having single-stranded polynucleotides of about 100 nucleotides. Specifically, Bao et al teach an array comprising cDNA and oligomers (Column 6, lines 32-34) wherein the cDNA target elements are more than 400 bp (Column 8, lines 45-54) and the oligomers are less than 100bp, (Column 8, lines 27-31). Bao et al teach the target element**s** comprise either genomic DNA, oligomer or cDNA nucleic acids or a mixture of the two. While this passage does not specifically state members of the mixture are located at independent features, it clearly suggests such independence. Bao et al further teach the array wherein the target elements comprise full length and partial length cDNAs from about 100bp to 5,000bp (Column 8, lines

45-48) and wherein the partial cDNAs are synthesized as oligos of 8-100bp (Column 8, lines 27-42).

Bao et al clearly teaches the combination of different types of nucleic acids on the array which suggests their immobilization to independent features as claimed (Column 3, line 56-Column 4, line 5; Column 6, lines 32-34; Column 10, lines 31-28 and Claim 5). Furthermore, arrays comprising combinations of oligonucleotides and cDNAs were well known in the art at the time the claimed invention was made a taught by Bobrow et al (Column 3, liens 30-35 and Claim 1).

Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Bao et al and Bobrow et al to provide arrays comprising oligonucleotides and cDNAs as claimed based on the clear suggestion to do so by Bao et al (Column 3, line 56-Column 4, line 5; Column 6, lines 32-34; Column 10, lines 31-28 and Claim 5).

Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the sequence length of Bao et al because they specifically teach that one of ordinary skill in the art would adjust the sequence length to provide the sequence information required (Column 8, lines 23-27). Furthermore, Bao et al teach that a target sequence will be broken in to fragments of different lengths and complexity (Column 8, lines 16-21). And one of skill would adjust fragment lengths to optimize hybridization and signal (Column 8, lines 23-27). Hence, one of ordinary skill in the art would have been motivated to provide an array of cDNA fragments of differing lengths (i.e. more than 400bp and less than 100bp) as suggested by Bao et al for the expected benefit of analyzing gene expression under optimized conditions as taught by Bao et al (Column 8, lines 16-26).

The burden is on applicant to show that the claimed ranges are either different or non-obvious over that of Bao et al.

Regarding Claims 2 and 3, Bao et al teach an array comprising cDNA and oligomers (Column 6, lines 32-34) wherein the cDNA target elements are more than 400 bp (Column 8, lines 45-54) and the oligomers are less than 100bp, (Column 8, lines 27-31) but they do not teach a ratio of short to long polynucleotides. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made, based on experimental design wherein expressed sequences are of interest, to provide an array comprising the claimed ratios. For example, an experiment designed to analyze expressed sequences of at least 400 nucleotides, an array comprising mostly sequences of at least 400 nucleotides would provide optimal analysis of the 400 nucleotide + sequences. Therefore, one skilled in the art would have been motivated to design the array having a short (less than 100) to long (at least 400) polynucleotide ratio of at least 1:10 or 1:20 to thereby optimize experimental condition and maximize experimental results.

Regarding Claim 5, Bao et al disclose the array wherein the first polynucleotides are from enzymatic processing (i.e. cloning) and the second polynucleotides are synthetic (i.e. obtained from commercial sources) (Column 8, lines 445-65). While Bao et al teaches the claimed process for making the first and second polynucleotides, it is noted that the claimed process for making the polynucleotides does not limit the polynucleotides.

Regarding Claim 6, Bao et al disclose the array wherein the first polynucleotides have a length of at least 500 nucleotides (Column 8, lines 55-58).

Regarding Claim 7, Bao et al disclose the array wherein the first polynucleotide cDNAs have a length of at least 1000 nucleotides (Column 8, lines 45-48) and the oligomeric target elements preferably range in size from 20-80 nucleotides (Column 8, lines 27-28). Furthermore, they teach that one of ordinary skill would adjust the lengths to optimize hybridization for any given hybridization (Column 8, lines 16-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cDNA and oligomer target elements of Bao et al and to provide the microarray with target

elements of more than 1000 and no more than 80 nucleotides as suggested by Bao et al (Column 8, lines 45-48) to thereby optimize the hybridization based on the desired procedure as taught by Bao et al (Column 8, lines 16-26).

Regarding Claim 8, Bao et al disclose the lengths exclude stilt portions i.e. Bao et al teach the polynucleotides are attached to the support (Column 11, lines 50-54) and do not teach the polynucleotides comprise stilts. Therefore, the polynucleotide length excludes a stilt portion.

Regarding Claim 9, Bao et al disclose the array wherein the features are arranged in a rectangle (Fig. 1A).

Regarding Claim 10, Bao et al disclose the features are arranged in lines (Fig. 1A) with at least some of the lines including features of both first and second sets i.e. the target elements are interspersed (Column 10, lines 31-38).

Regarding Claim 14, Bao et al disclose the array wherein the sequence of the second polynucleotide is contained within the first polynucleotide i.e. the array wherein the target elements comprise full length and partial length cDNAs and wherein the oligomers are sequence is derived from EST database (Column 8, lines 45-48) whereby the oligomer are within a cDNA sequence.

Regarding Claim 38, Bao et al disclose the microarray wherein features have the same polynucleotide i.e. array manufacture via deposition of a different nucleic acid at each spot (Column 9, line 66-Column 10, line 10).

Regarding Claim 41, disclose an array comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides and a second set of features having single-stranded polynucleotides of about 100 nucleotides. Specifically, Bao et al teach an array comprising cDNA and oligomers (Column 6, lines 32-34) wherein the cDNA target elements are more than 400 bp (Column 8, lines 45-54) and the oligomers are less than 100bp, (Column 8, lines 27-31) wherein the sequence of the second polynucleotide is contained within the first

polynucleotide i.e. the array wherein the target elements comprise full length and partial length cDNAs (Column 8, lines 45-48)

and wherein each feature contains only one sequence i.e. array manufacture via deposition of a different nucleic acid at each spot (Column 9, line 66-Column 10, line 10).

Responses to Arguments

6. Applicant asserts that the cited passage teaches target elements comprising a mixture of both oligomers and cDNA but does not teach a target element comprising oligomers independent from the target element comprising cDNA as newly claimed. The argument has been considered but is not found persuasive. As cited by application, the passage states "The nucleic acid target elements comprise either genomic DNA, oligomer or cDNA nucleic acids or a mixture of the two." In contrast to Applicant's assertion, the passage does not teach **a** target element comprises a mixture of oligomers and cDNAs, but instead teaches target element**s** comprise a mixture i.e. a plurality of element**s** have a mixture (i.e. different) members selected from the group of genomic DNA, oligomers or cDNA.

Furthermore, as cited above, Bao et al teach the array wherein the target elements comprise full length and partial length cDNAs from about 100bp to 5,000bp (Column 8, lines 45-48) and wherein the partial cDNAs are synthesized as oligos of 8-100bp (Column 8, lines 27-42). Hence, they teach an embodiment wherein elements comprise cDNAs and oligos i.e. partial cDNAs

Applicant argues that the teaching of Bao would have led one of ordinary skill *to try* but would not have led one *to* the instantly claimed invention. The argument has been considered but is not found persuasive because as stated above, Bao clearly teaches a combination of sequences of differing length on the array and further suggests the combination include cDNAs and oligos (Column 6, lines 32-34 and Column 8, lines 39-44) and further defines the lengths of the cDNAs and oligos (Column 8, lines 27-54) obviating the instant invention.

Applicant argues that Bao does not teach a sequence of a second polynucleotide is contained within a cDNA molecule sequence present in different elements as claimed in Claim 14 and 41. The argument has been considered but is not found persuasive because the argument is not commensurate in scope with the claims. The claim requires "the sequence of a second polynucleotide is contained within a cDNA. The claims are not limited to the second polynucleotide or the cDNA of Claim 1. Furthermore, the claims are not limited to the second polynucleotide of Claim 1 be within the cDNA of Claim 1. In contrast, the claims merely require a second polynucleotide sequence be within a cDNA. Hence, any cDNA in the array of Bao has a polynucleotide and/or second polynucleotide therein.

7. Claims 11-13, 15-20 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al (U.S. Patent No. 6,251,601, filed 2 February 1999) in view of CLONTECHniques (July 2000).

Regarding Claims 11-13 and 39-40, Bao et al disclose a microarray comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides (i.e. genomic DNA target elements, Column 8, lines 55-58) and a second set of features having single-stranded polynucleotides of about 100 nucleotides (i.e. cDNA target elements, Column 8, lines 45-48) wherein the microarray comprises both genomic DNA and cDNA target elements (Column 10, lines 31-35 and Claim 5) but they do not teach the array comprising a second set of features wherein the sequences of the second set of features is not within the first polynucleotide sequence. However, Clontech teaches a similar microarray comprising a second set of polynucleotides wherein the second set comprises control sequences not found in the first set of polynucleotides (right column and Fig. 1). It would have been obvious to one of

ordinary skill in the art at the time the claimed invention was made to apply the control probes of Clontech to the kit of Bao et al for the expected benefit of providing means for troubleshooting hybridizations as taught by Clontech (last paragraph).

Regarding Claim 15, Bao et al disclose an array comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides and a second set of features having single-stranded polynucleotides of about 100 nucleotides. Furthermore, they teach the microarray and reagents for using the array combined into a kit format (Column 14, line 63-Column 15, line13) but they do not specifically teach the reagents comprise polynucleotide controls at least 70% complementary to the second polynucleotides. However, microarray kits comprising control probes complementary to control polynucleotides on the microarray were well known in the art at the time the claimed invention was made as taught by Clontech. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the control probes of Clontech to the kit of Bao et al for the expected benefit of providing means for troubleshooting hybridizations as taught by Clontech (last paragraph).

Regarding Claim 16, Clontech teaches that the control probes are complementary to control polynucleotides on the microarray (last paragraph).

Regarding Claim 17, Clontech teaches that the control probes are labeled (last paragraph).

Regarding Claim 18, Clontech teach that the ratio of first set of features (i.e. target-specific) to the second set of features is at least 10/1 (i.e. the microarray comprises two control spots, Fig. 1 and last paragraph).

Regarding Claim 19, Clontech teach that the ratio of first set of features (i.e. target-specific) to the second set of features is at least 20/1 (i.e. the microarray comprises two control spots, Fig. 1 and last paragraph).

Regarding Claim 20, Clontech teaches the kit comprises instructions (right column).

Response to Arguments

8. Applicant argues that Clontech does not overcome the deficiencies of Bao. The argument is not found persuasive for the reasons stated above regarding Bao.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
August 12, 2004